510(k) SUMMARY

as required per 807.92(c)

DEC 21 2000

Submitters Name, Address:

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879
Official Correspondent: David Simard, Director
Quality Assurance & Regulatory Affairs
Contact person for this submission: Penelope H. Greco
Date submission was prepared: October 12, 2000

Trade Name, Common Name and Classification Name:

A. Trade Name:

Siemens INFINITY Modular Monitors (SC 7000 / SC 9000XL / SC 8000)

B. Common Name, Classification Name, Class and Regulation Number:

Common Name	Product Code	Class	Regulation Number
Monitor, Physiological, Patient (with arrhythmia detection or alarms)	MHX	III	21 CFR 870.1025
Arrhythmia detector & Alarm	74DSI	III	21 CFR 870.1025

Legally Marketed Device Identification:

INFINITY SC 8000 Monitor, 510(k) K983632 / K990563
INFINITY SC 7000 / SC 9000XL Modular Monitors, 510(k K982730 / 980882

Description of Modification:

This submission addresses software modifications that add the following features to the INFINITY modular monitors when set to OR mode:

1. Alarms for Anesthesia
   In OR mode anesthesia-specific alarm modifications have been added to avoid nuisance alarms.
2. Cardiac Bypass Mode (CBM)
   The user selectable cardiac bypass mode is for use in the OR mode during cardiac bypass surgeries only.

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS 16 Electronics Avenue Danvers, MA 01923 Tel: (978) 907-7500 Fax: (978) 750-6879

Intended Use:
The INFINITY Modular Monitors are intended for multi-parameter patient monitoring. The devices will produce visual and audible alarms if any of the physiological parameters monitored vary beyond preset limits and timed or alarm recordings will be produced. These devices will connect to a Siemens R50 Bedside recorder, either directly or via the INFINITY Network.

Assessment of non-clinical performance data for equivalence: See Section K

Assessment of clinical performance data for equivalence: Not applicable

Biocompatability: Not applicable

Sterilization: Not applicable

Standards and Guidances: See Declaration of Conformity, Section K

COMPANY CONFIDENTIAL

Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923
Tel: (978) 907-7500
Fax: (978) 750-6879

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Ms. Penelope Greco
Siemens Medical Systems, Inc.
Electromedical Systems Group, PCS
16 Electronics Avenue
Danvers, MA 01923

Re: K003243
Trade Name: Siemens INFINITY Modular Monitors
SC 7000 / SC 9000XL / SC 8000
Regulatory Class: III
Product Code: MHX
Dated: November 20, 2000
Received: November 21, 2000

Dear Ms. Greco:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003243

Device Name: Siemens INFINITY Modular Monitors (SC 7000 / SC 9000XL / SC 8000)

Indications for Use:

The INFINITY Modular monitors are capable of monitoring:

- Heart rate
- Respiration rate
- Invasive pressure
- Non-invasive pressure
- Arrhythmia
- Temperature
- Cardiac output
- Arterial oxygen saturation
- Pulse rate
- Apnea
- ST Segment Analysis
- 12-Lead ST Segment Analysis
- tcpO2/tcpCO2
- EEG signals
- FiO2

With the MultiGas and MultiGas+ modules the monitors are capable of measuring respiration rate, Inspired and expired Carbon Dioxide (CO2), inspired and expired Oxygen (MultiGas+ only), average inspired Oxygen (MultiGas only), inspired and expired gas concentrations of Enflurane, Halothane, Isoflurane, Desflurane, Sevoflurane, and Nitrous Oxide.

With etCO2 the monitors can measure end tidal carbon dioxide, inspired carbon dioxide, and respiration rate in either mainstream or side-stream measurement mode

The monitors can interface with specific third party devices via an MIB protocol converter.

The devices are intended to be used in the environment where patient care is provided by Healthcare Professionals, i.e. Physicians, Nurses, and Technicians, who will determine when use of the device is indicated, based upon their professional assessment of the patient's medical condition.

The devices are intended to be used on Adult, Pediatric and Neonatal populations, *with the exception of the parameter Cardiac Output and ST Segment Analysis which are intended for use in the adult and pediatric populations only; Arrhythmia which is not intended for use in neonatal mode; and tcpO2 which is to be used in the neonatal population only when the patient is not under gas anesthesia.*

MRI Compatibility Statement:
The INFINITY Modular Monitors are not compatible for use in a MRI magnetic field.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Division of Cardiovascular & Respiratory Devices
(k) Number K003243